

Attachment #5: Additional Technical Proposal Instructions

The following additional Technical Proposal instructions reflect the requirements of the Request for Proposal (RFP) and are meant to provide additional instructions as well as a uniform format for technical proposals. The information requested in these instructions should be used as a guide for formatting and preparing the proposal. Offerors shall follow the instructions in Section L of the solicitation, plus include the information requested in this Attachment..

Offerors are advised to give careful consideration to the Statement of Work (SOW), all reference material, and attachments, the technical evaluation criteria, and the RFP as a whole, in the development of their Technical Proposal.

Offerors who propose subcontracts to perform portions of the Statement of Work should clearly identify the specific sections for which they plan to utilize subcontractors, as well as the method and level of integration between the prime and subcontractor(s), and the expected advantages of such an approach.

1. GENERAL NOTES

All Offerors must adhere to the following page limitations:

- A. TECHNICAL PROPOSAL: Not-to-exceed a total of 75 pages not including appendices and attachments. Pages in excess of the page limitation will be removed from the proposal and will not be read, considered, or evaluated. The Technical Proposal must be signed by an authorized Business Representative (person authorized to negotiate and sign on behalf of the organization. The evaluation will be conducted on the technical proposal which may not exceed 75 pages plus any additional attachments and appendices as stated below.
- B. APPENDICES AND ATTACHMENTS: This includes the Title and Back Page; NIH-2043; Table of Contents; Section Dividers that do not contain information other than title of Section; Resumes/Curriculum Vitae of other key personnel (same information and format as used for the PI); certificates and licensures, examples of protocols, Standard Operating Procedures (SOP), Health and Safety Manual, letters of commitment by proposed consultants and subcontractors. Only this information may be in addition to 75 page limit for the Technical Proposal

2. FORMATTING AND LAYOUT

Use your usual word processing and spreadsheet programs to prepare the technical and business proposals using the format below:

- Type size must be 10 to 12 points.
- Type spacing should be no more than 15 characters per inch. Within a vertical inch, there must be no more than six lines of text.
- Print margins must be at least one inch on each edge of the paper.
- Print setup should be single-sided on standard letter size paper (8.5 x 11").
- Offerors shall NOT use 8.5 x 14 legal size paper.
- Proposals shall NOT include links to Internet Web site addresses (URLs) or otherwise direct readers/reviewers to alternate sources of information.

- Additional appendices and attachments may be added as needed per item 1.B above.
- The proposal with pagination, including appendices and attachments, shall be formatted sections, cross referenced, and include a detailed Table of Contents with page references.

3. **TECHNICAL DISCUSSIONS**

A detailed technical plan must be submitted in the Offeror's Technical Proposal indicating how each aspect of the Statement of Work (SOW) is to be accomplished. Your technical approach should be in as much detail as necessary to fully explain your proposed technical approach or method. The Technical Proposal should reflect a clear understanding of the nature of the work being undertaken.

The Offeror shall demonstrate their understanding and provide their recommended approach (i.e. the 'how') to each major project task area. It is critical that the offeror demonstrate their regulatory and operational understanding of the 'why' behind each task area:

A. Task 1: Initial Transition:

The Contractor shall provide a 60-day Initial Transition plan to ensure the orderly, efficient and safe transition of all contract activities and materials within with their proposal. The plan shall incorporate phasing in/out from the incumbent contractor to the successful awardee. The transition plan shall also include an overview, goals, level of effort, timelines, major milestones, communication plan, methodology and risk assessment.

The Initial Transition plan shall at minimum address the following areas:

- Staff recruitment
- Staff orientation to project
- Staff training for specific duties assigned
- Cross training
- IT software and data transfer

Offerors are encouraged to identify and provide a plan to address other common and/or CIRB centric transition challenges that might be anticipated that are not included in the above.

B. Task 2: Manage and provide administrative and regulatory support for three Central Institutional Review Boards (adult phase 3 and large phase 2 trials; early 1 and 2 phase trials; and pediatric trials)

- a. The Contractor shall provide their regulatory and operational understanding capability to meet all sub-tasks.

C. Task 3: Establish and Support a new CIRB for review of DCP trials.

- a. The Contractor shall provide a plan to establish and maintain a new DCP CIRB within 120 days of contract award. The plan shall include an overview, goals, level of effort/staffing, timelines, major milestones, communication plan, methodology and risk assessment. The plan shall focus on establishing a DCP CIRB utilizing procedures, policies, system

and infrastructure consistent to that provide for the other Boards. The Contractor shall identify any unique challenges or requirements for a DCP Board. The plan shall describe how the DCP Board will be maintained once established.

D. Task 4: Manage and provide administrative and regulatory support for CIRB review of enrolled institution's local context considerations.

- a. The Contractor shall provide their regulatory and operational understanding capability to meet all sub-tasks in this area.

E. Task 5: Enroll new institutions to the CIRB Initiative.

- a. The Contractor shall provide their solutions to address each sub-task in this area.

F. Task 6: Manage and support new and already enrolled institutions.

- a. The Contractor shall provide their solutions to address each sub-task in this area.

G. Task 7: Provide I.T. software and support all operations.

The Contractor shall demonstrate their understanding to each sub-task in this area with emphasis on software development, maintenance, management, and IT governance consistent with the Department of Health and Human Services (HHS) Enterprise Performance Life Cycle (EPLC) practices to enhance Information Technology (IT) governance (<http://www.hhs.gov/ocio/eplc/index.html>)

The following is provided as background information related to IT system and data transfer:

- a. The incumbent Contractor utilizes an MS Access™ database to track Helpdesk requests. Custom code and report templates shall be transferred from the incumbent to the successful awardee. The Contractor shall have an electronic Helpdesk tracking system that provides similar report and tracking capabilities.
- b. The incumbent Contractor utilizes an MS Access™ database to monitor internal quality assurance. This system, data, and reports were developed using Government resources. Custom code and report templates shall be transferred from the incumbent to the successful awardee.

H. Task 8: Communicate with NCI and stakeholders regarding all aspects of the CIRB Initiative.

- a. The Contractor shall provide their solutions to address each sub-task in this area.
- I. Task 9: Implement and manage an Initiative-wide Quality Improvement Plan.
 - a. The Contractor shall provide their solutions to address each sub-task in this area. In addition the contractor shall identify potential challenges, risks, and opportunities for the CIRB initiative. The Contractor shall provide a recommendation(s) to address each issue identified.
- J. Task 10: Maintain AAHRPP Accreditation per AAHRPP requirements.
 - a. The Contractor shall provide their solutions to address each sub-task in this area.
- K. Optional Task 1: Phase-Out Transition.
 - a. The Contractor shall provide their solutions to address each sub-task in this area.
- L. Optional Task 2: Establish and support additional CIRB(s)
 - a. The Contractor shall provide their solutions to address each sub-task in this area.

It is recognized that a single institution may not have the expertise and facilities required to perform all requirements of the Statement of Work. Therefore, the Offeror may propose to subcontract a portion of the work. If a subcontractor is proposed, similar technical information must be provided in the Technical Proposal as that required for the offeror (i.e., technical approach, methods, experience, personnel qualifications, facilities, resources, etc.). The relationship between the proposed subcontractor and the Offeror must be clearly delineated.

4. EXPERIENCE AND CAPABILITIES OF PERSONNEL

The Technical Proposal should include all information relevant to document individual training, education, experience, qualifications and expertise necessary for the successful completion of all contract requirements. Clearly identify who is to be assigned as Key Personnel. Limit Curriculum Vitae (CVs) for Key Personnel to 2-3 pages and provide selected references for publications relevant to the scope of the RFP. For proposed staff, please include experience with projects of similar scope, size and complexity. CVs for all non-key Personnel shall be limited to one-page.

- A. Project Manager (Key Personnel): Describe the education, training, experience, expertise, qualifications, and percentage of effort of the proposed Project Manager (PD) to lead and direct the activities to be carried out under this contract, including: managing an interdisciplinary team in a distributed environment; multi-center clinical trial experience; IRB and regulatory experience; and use/application of common project management approaches to maximize project quality, effectiveness and efficiency. The PM shall have extensive experience with a project of similar size and

scope. The qualification and experience of the PM should be discussed in terms how they are appropriate to the management of any planned subcontracts. Discuss how the technical and operational planning and implementation will be managed by the PM.

- B. CIRB Administrator and CIRB Coordinator: Describe the education, training, experience, expertise, qualifications, and percentage of effort of the proposed CIRB Administrator and Coordinator to lead and direct the activities to be carried out under this contract, including: managing an interdisciplinary team in a distributed environment; multi-center clinical trial experience; IRB, including 'Central' IRB, experience; regulatory experience; AAHRPP Accreditation process and requirements. The CIRB Administrator and Coordinator shall have extensive experience with a project of similar size and scope. The qualification and experience should be discussed in terms of how they are appropriate to the management of any planned subcontracts. Discuss how the regulatory, operational and technical planning and implementation will be managed by the CIRB Administrator and Coordinator.
- C. Quality Assurance Manager(s): Describe the education, training, experience, expertise, qualifications, and percentage of effort of the proposed Quality Assurance Manager(s) to lead and direct the activities to be carried out under this contract, including: designing and monitoring processes for quality assurance; ability to measure, monitor, and optimize quality in non-IRB related processes; developing quality assurance plans; training and managing staff; initiating innovative approaches to problem solving when quality metrics indicate a deficiency exists; and regulatory experience. The Quality Assurance Manager(s) shall have extensive experience with a project of similar size and scope. The qualification and experience should be discussed in terms of how they are appropriate to the management of any planned subcontracts. Discuss how the regulatory, operational and technical planning and implementation will be managed by the Quality Assurance Manager(s).
- D. IT Manager: Describe the education, training, experience, expertise, qualifications, and percentage of effort of the proposed IT Manager, to lead and direct the activities to be carried out under this contract, including: managing an interdisciplinary team in a distributed environment; multi-center clinical trial experience; IT development and management following Capability Maturity Model Integration (CMMI) and Department of Health and Human Services (HHS) Enterprise Performance Life Cycle (EPLC); development and implementation of Open-source systems; and IT Security, back-up and disaster recovery. The IT Manager shall have extensive experience with a project of similar size and scope. The qualification and experience of the IT Manager should be discussed in terms of how they are appropriate to the management of any planned subcontracts. Discuss how the technical and operational planning and implementation will be managed by the IT Manager.
- E. Additional Personnel: Offerors staff should include experienced personnel that can support and compliment key personnel in achieving the project goals and areas.
- F. Staffing plan: A staffing plan/matrix outlining areas of responsibility, reporting and level of effort shall be provided. The staffing plan shall demonstrate cross training and back-up coverage. If a geographically dispersed team is proposed then a

description of how the team will collaborate with each other and NCI staff shall be provided.

5. TECHNICAL APPROACH

Offerors shall submit a proposal that addresses all Tasks in the Statement of Work. Only proposals from offerors who demonstrate the capability to perform all aspects of the Statement of Work, either at their institution or through their subcontractors, will be considered for award.

Subcontracts - In the event that the offeror does not have facilities, equipment, or personnel for performing any component of the described in each section, then the offeror shall be prepared to implement the work through a suitable subcontractor(s). The proposal shall include the sub-contractors prior experience with projects of similar size and scope to those which they are assigned. Letters of commitment from and qualifications of all proposed subcontractors shall be included in the proposal. The offeror shall describe any previous working relationship with proposed subcontractors. Furthermore, the offeror shall address how they will handle privacy of contract issues (i.e., the offeror should explain how information will flow between the NCI, the prime Contractor, and any subcontractors since the prime contractor's presence is required for any discussions).

6. FACILITIES AND EQUIPMENT

The Offeror shall provide a description of their facilities and equipment that will be provided to support all facets of the proposal. The Contractor shall emphasize facilities, equipment processes, and procedures that address/promote/ensure:

- A. Data security.
- B. Storage capability.
- C. Telephone helpdesk capability
- D. Continuity of services after a natural disaster

In addition, any specialized facilities and equipment necessary to address specific technical requirements shall be provided for each section of the SOW. If a geographically dispersed team is proposed then a description of the tools to be utilized to facilitate team will collaborate with each other and NCI staff shall be provided.